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Everolimus-Eluting Versus Biolimus-Eluting Coronary Stent Implantation in Patients With and Without Diabetes Mellitus

Running head: SORT OUT VIII Diabetes Substudy

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Abstract

Diabetes mellitus is associated with a higher risk of target lesion revascularization (TLR) after percutaneous coronary intervention. We compared clinical outcomes in patients with and without diabetes mellitus, treated with everolimus-eluting stents (EES; Synergy; Boston Scientific, Marlborough, MA, USA) or biolimus-eluting stents (BES; BioMatrix NeoFlex; Biosensors Interventional Technologies Pte Ltd., Singapore). In total, 2,764 patients were randomized to stent implantation with EES (n=1,385, diabetes: n=250) or the BES (n=1,379, diabetes: n=262), stratified by sex and diabetes. The primary endpoint, target lesion failure (TLF), was a composite of cardiac death, target-lesion myocardial infarction, or TLR at 12 months. Secondary endpoints included individual components of TLF, all-cause death, and stent thrombosis. TLF was 2.1% lower in the EES vs the BES groups in patients with diabetes (3.6% vs 5.7%; RR 0.61, 95% confidence interval [CI] 0.27-1.41) and similar in patients without diabetes (4.1% vs 4.0%; RR 0.99, 95% CI 0.66-1.51). Among patients with diabetes, the point estimates of the individual components of TLF also favored the EES but confidence intervals were wide. No interaction between stent type and presence of diabetes was found. The current subgroup analysis found that a thin-strut EES as compared to a thicker-strut BES had a numerically lower TLF rate among patients with diabetes, but the subgroup analysis was underpowered for definite conclusions.

Key Words

drug-eluting stent, percutaneous coronary intervention, randomized clinical trial, diabetes

Introduction

Diabetes mellitus is associated with an increased risk of restenosis and major adverse cardiovascular events after percutaneous coronary intervention (PCI).[1-3] Guidelines recommend implantation of new-generation drug-eluting stents (DES) in diabetes patients undergoing PCI due to higher safety and efficacy compared to early-generation DES and bare-metal stents.[4] The Scandinavian Organization for Randomized Trials with Clinical Outcome (SORT OUT) VIII trial compared 2 new-generation DES with biodegradable polymers: the thin-strut platinum-chromium everolimus-eluting stent (EES; Synergy) versus the stainless-steel biolimus-eluting stent (BES; BioMatrix NeoFlex). At 12-month follow-up, EES was non-inferior to BES with respect to target lesion failure (TLF) in routine clinical care patients.[5] In this prespecified substudy, we examined 12-month clinical outcomes in patients with and without diabetes treated with EES or BES.

Methods

SORT OUT VIII is a randomized, multi-centre, all-comers, two-arm, non-inferiority trial comparing EES to BES in treating coronary and graft lesions. Patients were eligible if they were ≥18 years old, had chronic stable coronary artery disease or acute coronary syndromes, and ≥1 coronary or graft lesion with >50% diameter stenosis. A detailed description of study protocol, including inclusion and exclusion criteria, was reported in the main publication.[5] This trial was registered with ClinicalTrials.gov (NCT02093845).

Block randomization by centre was used to assign patients in a 1:1 ratio to receive the EES (Synergy; Boston Scientific, Marlborough, MA, USA) or the BES (BioMatrix NeoFlex; Biosensors Interventional Technologies Pte Ltd., Singapore). The allocation sequence was computer-generated and stratified by sex and presence of diabetes. Patients were considered

to have diabetes if they received glucose-lowering medications or reported dietary treatment for diabetes combined with haemoglobin A1c above the diagnostic threshold for diabetes.[3,6-8]

The primary endpoint, TLF, was a composite of safety (cardiac death and myocardial infarction [MI] not clearly attributable to a non-target lesion) and efficacy (clinically indicated target lesion revascularization [TLR]) within 12 months. Secondary endpoints were: cardiac death; all-cause death; MI; clinically indicated TLR; clinically indicated target vessel revascularization (TVR); definite, probable, or possible stent thrombosis; device delivery failure; and patient-related composite endpoint defined as a combination of all-cause death, any MI, and any clinically indicated revascularization (TVR and non-TVR).

Distributions of continuous variables in the study groups were compared using 2-sample t test (or Cochran test in the case of unequal variance) or the Mann-Whitney U test, depending on whether data followed a normal distribution. Distributions of categorical variables were evaluated using the χ^2 test. Follow-up began on the date of the index PCI procedure and continued until the date of an endpoint event, death, emigration, or 12 months after stent implantation, whichever came first. Cumulative incidence curves were constructed based on cumulative incidence of endpoint events, accounting for competing risk of death. Rate ratios (RRs) were calculated using BES as reference. All analyses were performed following intention-to-treat principles. P-values were 2-sided with a significance threshold of <0.05. We used SAS version 9.2 (SAS Institute Inc., Cary, NC, USA) for all statistical analyses.

Results

A total of 2,764 patients were included in the study. In the BES group, 2 patients were censored due to emigration (on day 42 and 307). None were lost to follow-up.

Baseline patient characteristics (Table 1) and procedural characteristics (Table 2) were well balanced in both diabetes and non-diabetes patients treated with EES versus BES. Compared to patients without diabetes, those with diabetes had higher body mass index, were more often treated for hypertension and hypercholesterolemia, and more frequently had a history of MI, PCI, and coronary artery bypass grafting. Furthermore, diabetes patients had a greater burden of comorbidity, and fewer were active smokers. Patients with diabetes were more commonly treated with >1 stent and fewer received bivalirudin compared to patients without diabetes, the latter reflecting a lower number of STEMI patients in the diabetes subgroup.

The clinical endpoints are presented in Figure 1. The cumulative risk of TLF is illustrated in Figure 2. At 12-month follow-up, TLF was 3.6% in the EES group and 5.7% in the BES group in patients with diabetes (RR 0.61, 95% confidence interval [CI] 0.27-1.41). In patients with diabetes, the RRs of secondary endpoints were in favor of the EES, but CI's were wide and none of the endpoints were statistically significant. Patients without diabetes had a similar risk of both TLF (4.1% with EES vs 4.0% with BES; RR 0.99, 95% CI 0.66-1.51) and the secondary endpoints. No interaction between stent type and presence of diabetes was found.

Discussion

This SORT OUT VIII substudy provides a 12-month head-to-head comparison of the Synergy EES and the BioMatrix NeoFlex BES in patients with and without diabetes. Our trial showed no significant differences between stent type neither for patients with diabetes nor for patients without diabetes. However, event rates were consistently lower in the EES group

compared to the BES group among patients with diabetes and the lack of significance may reflect insufficient power in a subgroup analysis.

SORT OUT VIII is the first trial comparing the EES vs BES.[5] These stents differ concerning strut thickness (74-79 μm vs 112 μm), absorption period of the polymer (~4 months vs ~6-9 months), stent material (platinum chromium vs stainless steel), and the eluted drug. Thinner stent struts have been associated with less thrombogenicity[9] and superior clinical outcomes with reduced risk of restenosis.[10,11] Accordingly, experimental results have demonstrated less acute thrombogenicity of the thin-strut Synergy EES compared to the BioMatrix BES.[12] In the main SORT OUT VIII publication, however, we found non-inferiority between the 2 DES.[5]

Diabetes patients may serve as a "stress test" when evaluating the clinical performance of stents due to increased risk of restenosis and major adverse cardiovascular events after PCI.[1-3] Thus, our study suggests a potential 39% relative risk reduction of TLF with EES compared to BES, although the wide CIs make this point estimate uncertain. Moreover, as illustrated in Figure 1, the point estimates favor EES for all endpoints among patients with diabetes. Additionally, rate of stent delivery failure was twice as high in the BES treated diabetes patients. This is likely associated with BES having thicker struts and thus being more difficult to advance in complex lesions.

As previously demonstrated in other SORT OUT substudies, patients with diabetes showed greater differences between first-generation DES and second-generation DES than patients without diabetes.[6,7] Second-generation DES, however, have narrowed the gap between different DES, also in patients with diabetes.[8,13,14] In the SORT OUT III diabetes substudy, major adverse cardiac events differed between the Cypher sirolimus-eluting stent (SES) and the Endeavor zotarolimus-eluting stent (ZES) at 18-month follow-up (4.8% vs

18.3%) and 5-year follow-up (18.5% vs 28.4%).[6,7] Major adverse cardiac events occurring between 12 to 60 months follow-up, however, did not differ between SES and ZES (15% in both groups).[7] In the SORT OUT IV diabetes substudy, the Xience V EES had a 5.5% lower risk of major adverse cardiac events than the Cypher Select+ SES (10.3% vs 15.8%) at 18-month follow-up.[3] In SORT OUT VII, 2-year TLF rate was similar in diabetes patients treated with 2 new-generation DES (Orsiro SES 9.3% vs Nobori BES 9.4%), both using a bioarbsorbable polymer for drug delivery.[8] Finally, in the BIONICS trial, outcomes were similar between patients treated with ridaforolimus-eluting and zotarolimus-eluting stents at 2-year follow-up, regardless of diabetes status.[13] Here we found that TLF was numerically lower with the Synergy EES compared to the BioMatrix NeoFlex BES in patients with diabetes, which is comparable to the BIO-RESORT trial that also reported numerically fewer TLF events with the Synergy EES compared to the Resolute Integrity ZES (5.9% vs 8.1%) at 12-month follow-up in patients with diabetes.[15]

The present study has limitations. First, this subgroup analysis, as is any subgroup, would not have sufficient power in the individual subgroups. A sufficiently powered study (alpha 0.05, beta 0.2) in diabetes patients would require approximately 1600 diabetes patients per stent group to adequately confirm the observed 2.1% TLF difference. Second, the registry-based endpoint design with adjudication by an endpoint committee corresponds to outcome assessment in conventional randomized clinical trials, the only exceptions being stent thrombosis and TVR/TLR that were classified by 2 dedicated PCI operators.[5]

In conclusion, the SORT OUT VIII diabetes substudy showed no significant differences between the biodegradable-polymer Synergy EES and the biodegradable-polymer BioMatrix NeoFlex BES at 1-year follow-up in patients with and without diabetes.

Disclosures

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polymer zotarolimus-eluting stents in allcomers with coronary artery disease (BIO-RESORT): a three-arm, randomised, non-inferiority trial. *Lancet* 2016;388:2607-2617.

FIGURE LEGENDS

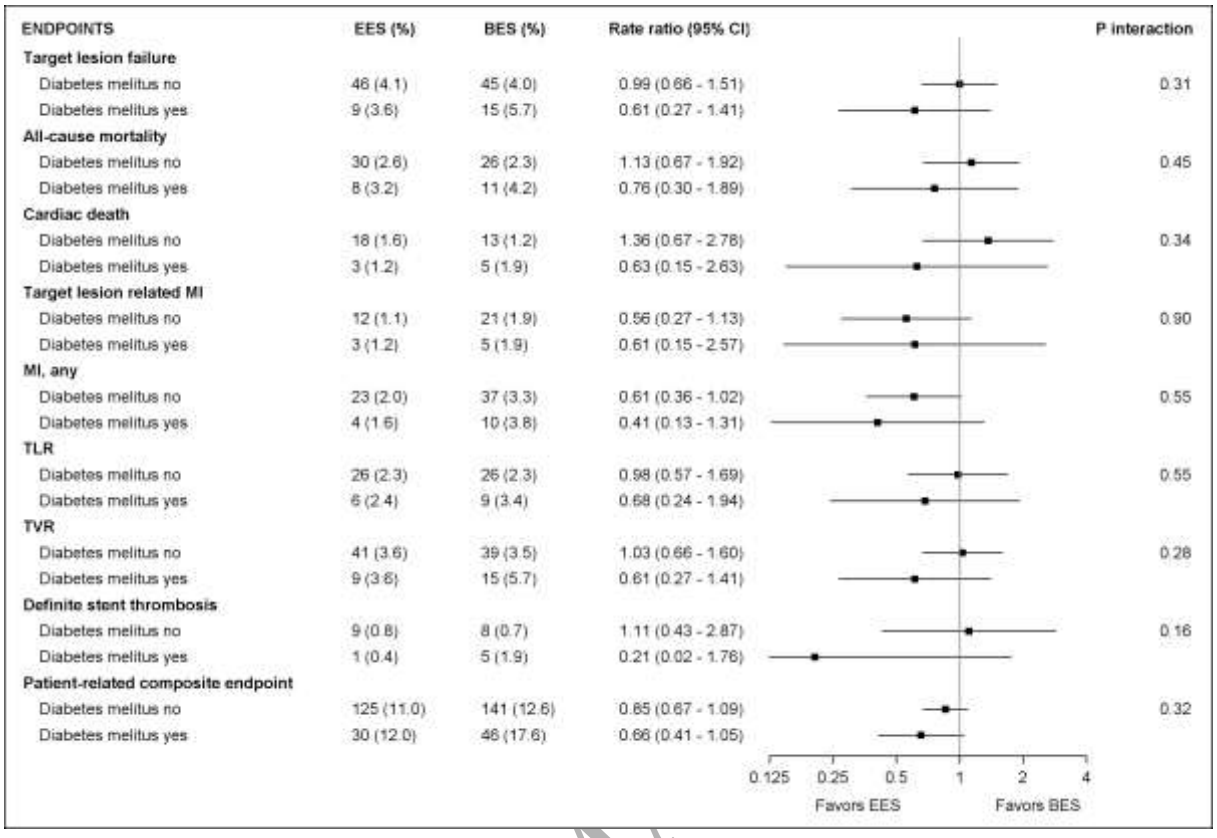

Figure 1. One-year clinical outcomes among randomized patients with and without diabetes mellitus treated with everolimus-eluting stents (EES) or biolimus-eluting stents (BES). CI = confidence interval; MI = myocardial infarction; TLR = target lesion revascularization; TVR = target vessel revascularization. Values are presented as number of patients (percentage).

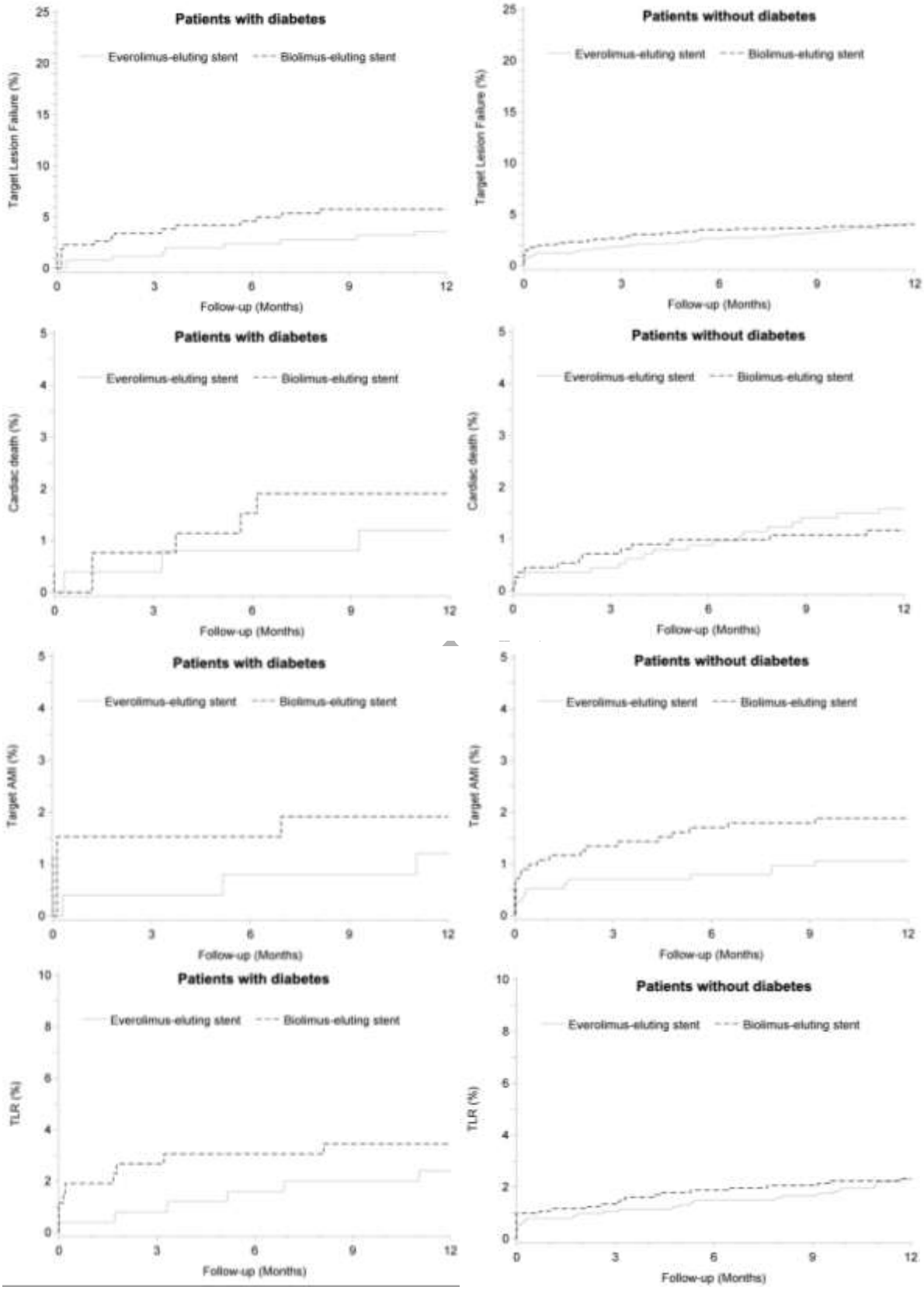

Figure 2. Event rates of target lesion failure and the individual components (cardiac death,

target vessel-related myocardial infarction, and target lesion revascularization [TLR]) in patients with and without diabetes after implantation with everolimus-eluting (solid line) or biolimus-eluting (dotted line) stents during 12-month follow-up. AMI = acute myocardial infarction.

Table 1. Baseline characteristics of patients with and without diabetes mellitus

Variable	Patients with diabetes			Patients without diabetes			P value diabetes vs non-diabetes
	Everolimus-eluting stent (n=250)	Biolimus-eluting stent (n=262)	P-value	Everolimus-eluting stent (n=1,135)	Biolimus-eluting stent (n=1,117)	P-value	
Age (years), mean±SD	66.6±11.3	67.1±10.7	0.62	66.3±11.1	66.1±10.6	0.78	0.09
Men	180 (72.0%)	194 (74.0%)	0.60	880 (77.5%)	862 (77.2%)	0.84	0.04
Current smoker	67 (28.4%)	55 (22.0%)	0.10	351 (32.5%)	330 (31.1%)	0.51	0.004
Body mass index, (kg/m^2), mean±SD	29.8±5.9	30.0±7.8	0.78	27.3±4.4	27.3±4.5	0.96	<0.001
Hypertension	185 (74.0%)	210 (80.2%)	0.25	592 (52.2%)	585 (52.4%)	0.11	<0.001
Hypercholesterolemia	187 (74.8%)	197 (75.2%)	0.97	561 (49.4%)	527 (47.2%)	0.42	<0.001
Previous myocardial infarction	60 (24.0%)	60 (22.9%)	0.79	181 (15.9%)	166 (14.9%)	0.57	<0.001
Previous percutaneous coronary intervention	55 (22.0%)	78 (29.8%)	0.13	191 (16.8%)	199 (17.8%)	0.81	<0.001
Previous coronary artery bypass grafting	40 (16.1%)	31 (12.0%)	0.18	104 (9.2%)	81 (7.3%)	0.11	<0.001
Clinical presentation			0.09			0.98	<0.001
ST-segment elevation myocardial infarction	32 (12.8%)	37 (14.1%)		255 (22.5%)	247 (22.1%)		
Non-ST-segment elevation myocardial infarction/unstable angina pectoris	96 (38.4%)	75 (28.6%)		370 (32.6%)	370 (33.1%)		
Stable angina pectoris	106 (42.4%)	136 (51.9%)		472 (41.6%)	460 (41.2%)		
Other	16 (6.4%)	14 (5.3%)		38 (3.3%)	40 (3.6%)		
Anti-diabetes treatment			0.07				
Diet-only	13 (5.2%)	21 (8.0%)					
Non-insulin medication	119 (47.6%)	145 (55.3%)					
Insulin (±non-insulin medication)	89 (35.6%)	77 (29.4%)					
Missing	29 (11.6%)	19 (7.3%)					
Comorbidity Index score			0.89			0.45	<0.001
0	62 (24.8%)	68 (26.0%)		681 (60.0%)	699 (62.6%)		
1-2	101 (40.4%)	108 (41.2%)		353 (31.1%)	327 (29.3%)		
≥3	87 (34.8%)	86 (32.8%)		101 (8.9%)	91 (8.1%)		

Values are presented as number of patients (percentage) unless otherwise stated.

Table 2. Baseline lesion and procedure characteristics of patients with and without diabetes mellitus

Variable	Patients with diabetes			Patients without diabetes			P value diabetes vs non-diabetes
	Everolimus-eluting stent (n=250)	Biolimus-eluting stent (n=262)	P-value	Everolimus-eluting stent (n=1,135)	Biolimus-eluting stent (n=1,117)	P-value	
Number of lesions	322	331		1,403	1,339		
Target lesions per patient			0.70			0.64	0.16
1	154 (62.6%)	157 (61.1%)		751 (66.3%)	758 (68.0%)		
2	61 (24.8%)	69 (26.8%)		248 (21.9%)	233 (20.9%)		
3	18 (7.3%)	24 (9.3%)		87 (7.7%)	79 (7.1%)		
>3	13 (5.2%)	7 (2.7%)		46 (11.8%)	44 (4.0%)		
Target lesion coronary vessel			0.70			0.45	0.10
Left main	10 (3.1%)	11 (3.3%)		33 (2.4%)	22 (1.6%)		
Left ant. descending	120 (37.3%)	137 (41.4%)		598 (42.6%)	575 (42.9%)		
Left circumflex	78 (24.2%)	72 (21.8%)		289 (20.6%)	303 (22.6%)		
Right	103 (32.0%)	104 (31.4%)		458 (32.6%)	414 (30.9%)		
Saphenous vein graft	11 (3.4%)	7 (2.1%)		25 (1.8%)	25 (1.9%)		
Lesion type			0.46			0.97	0.25
A	46 (14.3%)	46 (13.9%)		174 (12.4%)	172 (12.8%)		
B1	85 (26.4%)	106 (32.0%)		425 (30.3%)	398 (29.7%)		
B2	70 (21.7%)	64 (19.3%)		334 (23.8%)	314 (23.5%)		
C	121 (37.6%)	115 (34.7%)		470 (33.5%)	455 (34.0%)		
Long-term total occlusion lesions	16 (5.0%)	17 (5.1%)	0.94	63 (4.5%)	74 (5.6%)	0.21	0.96
Bifurcation lesions	60 (18.7%)	53 (16.0%)	0.37	231 (16.5%)	218 (16.4%)	0.90	0.59
Lesion length (mm), median: Q1-Q3	15.0 (10.0-22.0)	14.0 (10.0-20.00)	0.53	15.0 (11.0-20.0)	15.0 (10.0-21.0)	0.60	0.05
Reference vessel size, (mm), median: Q1-Q3	3.2 (3.0-3.7)	3.2 (3.0-3.5)	0.45	3.4 (3.0-3.7)	3.3 (3.0-3.6)	0.15	0.12
Total stent length (mm), median: Q1-Q3							
Per patient	24.0 (16.0-36.0)	24.0 (14.0-35.0)	0.52	21.0 (16.0-33.0)	23.5 (14.0-33.0)	0.18	0.64
Per lesion	19.0 (12.0-24.0)	18.0 (14.0-24.0)	0.40	20.0 (16.0-26.0)	18.0 (14.0-26.5)	0.30	0.02
>1 stent used	92 (37.4)	100 (38.9)	0.73	244 (21.5)	230 (20.6)	0.60	0.02
Maximum pressure (atm), median: Q1-Q3	18.0 (14.0-20.0)	17.0 (14.0-20.0)	0.19	16.0 (14.0-20.0)	16.0 (14.0-20.0)	0.23	0.09
Direct stenting	33 (10.4%)	37 (11.3%)	0.69	172 (12.3%)	175 (13.1%)	0.53	0.21
Stent delivery failure	4 (1.2%)	8 (2.4%)	0.26	25 (1.8%)	36 (2.7%)	0.11	0.69
Length of procedure (min), median: Q1-Q3	24.0 (16.0-36.0)	24.0 (14.0-35.0)	0.52	20.0 (13.0-33.0)	21.0 (14.0-33.0)	0.36	0.60
Fluoroscopic time (min), median: Q1-Q3	6.1 (3.9-10.1)	6.5 (3.8-11.0)	0.65	6.0 (3.3-10.7)	6.0 (3.5-11.0)	0.40	0.21
Contrast (ml), median: Q1-Q3	80.0 (50.0-110.0)	80.0 (50.0-120.0)	0.18	80.0 (50.0-110.0)	80.0 (50.0-125.0)	0.09	0.88
Use of glycoprotein IIb/IIIa inhibitors	6 (2.4%)	12 (4.6%)	0.18	31 (2.7%)	33 (3.0%)	0.75	0.42
Use of Bivalirudin	36 (15.9%)	32 (13.1%)	0.31	265 (25.0%)	249 (23.9%)	0.86	<0.001

Values are presented as number of patients (percentage) unless otherwise stated.
Q1 = 1st quartile; Q3 = 3rd quartile.